

CLEAN VERSION OF PENDING CLAIMS

PSORIASIS PATCH

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1. An adhesive patch comprising a flexible backing having a front side and a back side and a therapeutic formulation positioned on at least a portion of the front side of the backing, in at least a portion of the front side of the backing, or on and in at least a portion of the front side of the backing; wherein at least a portion of the backing is treated with a sizing agent such that the portion of the backing that is treated with the sizing agent has a surface energy of about 20 dynes/cm² to about 65 dynes/cm²; wherein the therapeutic formulation comprises:

a medicament selected from one or more topical psoriasis drugs, one or more topical dermatitis drugs, one or more topical eczema drugs, or a combination thereof;

a solvent that dissolves the medicament; and

a pressure sensitive adhesive.

2. The adhesive patch of claim 1 wherein the therapeutic formulation is partially embedded in at least a portion of the front side of the backing.

3. The adhesive patch of claim 1 wherein the therapeutic formulation is located on the entire surface of the front side of the backing.

4. The adhesive patch of claim 1 wherein the backing is porous.

5. The adhesive patch of claim 1 wherein the backing is vapor permeable.

6. The adhesive patch of claim 1 wherein the backing comprises water insoluble material.

7. The adhesive patch of claim 1 wherein the backing has a thickness of about 0.025 mm to about 1.25 mm.

8. The adhesive patch of claim 1 wherein the backing comprises a nonwoven fabric.

Fluorocar
solution

Hydrocortisone
acetate

Propylene
Carboxalate

Backing
Acrylic
ester
Copolym

9. The adhesive patch of claim 1 wherein the sizing agent is a fluorocarbon solution, a silicone-containing compound, or a combination thereof.

10. (Once amended) The adhesive patch of claim 9 wherein the backing that is treated with the fluorocarbon solution is VILMED™ M1585 W/HY, VILMED™ M1585H/HY, VILMED™ M1586 W/HY, VILMED™ M1586 H/HY, VILMED™ M1570, VILMED™ M1573 F, VILMED™ M1573 FH, VILMED™ M1577 F, VILMED™ M1578 F, VILMED™ M1578 FH, or a combination thereof.

11. The adhesive patch of claim 9 wherein the silicone-containing compound is a polydimethyl siloxane, a dialkylsiloxane, a dimethylsiloxo vinyl alkene, a dialkylsiloxo vinyl alkene, a dimethylsiloxo acrylate, a dialkylsiloxo acrylate, a vinyl terminated polydimethylsiloxane, a vinyl terminated polydialkylsiloxane, or a combination thereof.

12. The adhesive patch of claim 1 wherein the entire front side of the backing is treated with the sizing agent.

13. The adhesive patch of claim 1 wherein the sizing agent penetrates at least a portion of the underlying surface of the front side of the backing.

14. The adhesive patch of claim 1 wherein the sizing agent penetrates the entire underlying surface of the front side of the backing.

15. The adhesive patch of claim 1 wherein the entire backing is treated with the sizing agent.

16. The adhesive patch of claim 1 wherein the backing comprises polycellulose fibers, polyester fibers, polyurethane fibers, polyolefin fibers, polyamide fibers, cotton fibers, copolyester fibers, or any mixture thereof.

17. The adhesive patch of claim 1 wherein upon contact with skin, the backing retains the therapeutic formulation and the patch allows moisture from the skin to pass.

18. The adhesive patch of claim 1 wherein the topical psoriasis drug or the topical dermatitis drug is coal tar, pyrithione zinc, salicylic acid, selenium sulfide, a pharmaceutically acceptable salt thereof, or a combination thereof.

19. The adhesive patch of claim 1 wherein the topical psoriasis drug or the topical dermatitis drug is salicylic acid, or a pharmaceutically acceptable salt thereof.

20. The adhesive patch of claim 19 wherein the salicylic acid, or the pharmaceutically acceptable salt thereof is present in about 0.5 wt.% to about 5.0 wt.% of the therapeutic formulation.

21. The adhesive patch of claim 19 wherein the salicylic acid, or the pharmaceutically acceptable salt thereof is present in about 1.8 wt.% to about 3.0 wt.% of the therapeutic formulation.

22. The adhesive patch of claim 1 wherein the topical eczema drug is camphor, menthol, benzocaine, butamben picrate, dibucaine, dibucaine hydrochloride, dimethisoquin hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, tetracaine hydrochloride, benzyl alcohol, camphorated metacresol, juniper tar, phenol, phenolate sodium, resorcinol, diphenhydramine hydrochloride, tripeleannamine hydrochloride, hydrocortisone, hydrocortisone acetate, or a combination thereof.

23. The adhesive patch of claim 22 wherein the camphor is present up to about 3.0 wt.% of the therapeutic formulation and menthol is present up to about 1.0 wt.% of the therapeutic formulation; benzocaine is present in about 5.0 wt.% to about 20.0 wt.% of the therapeutic formulation; butamben picrate is present in about 0.5 wt.% to about 1.5 wt.% of the therapeutic formulation; dibucaine is present in about 0.25 wt.% to about 1.0 wt.% of the therapeutic formulation; dibucaine hydrochloride is present in about 0.25 wt.% to about 1.0 wt.% of the therapeutic formulation; dimethisoquin hydrochloride is present in about 0.3 wt.% to about 0.5 wt.% of the therapeutic formulation; dyclonine hydrochloride is present in about 0.5 wt.% to about 1.0 wt.% of the therapeutic formulation; lidocaine is present in about 0.5 wt.% to about 4.0 wt.% of the therapeutic formulation; lidocaine hydrochloride is present in about 0.5 wt.% to

about 4.0 wt.% of the therapeutic formulation; pramoxine hydrochloride is present in about 0.5 wt.% to about 1.0 wt.% of the therapeutic formulation; tetracaine is present in about 1.0 wt.% to about 2.0 wt.% of the therapeutic formulation; tetracaine hydrochloride is present in about 1.0 wt.% to about 2.0 wt.% of the therapeutic formulation; benzyl alcohol is present in about 10.0 wt.% to about 33.0 wt.% of the therapeutic formulation; camphor is present in about 0.1 wt.% to about 3.0 wt.% of the therapeutic formulation; juniper tar is present in about 1.0 wt.% to about 5.0 wt.% of the therapeutic formulation; phenolate sodium is present in about 0.5 wt.% to about 1.5 wt.% of the therapeutic formulation; resorcinol is present in about 0.5 wt.% to about 3.0 wt.% of the therapeutic formulation; diphenhydramine hydrochloride is present in about 1.0 wt.% to about 2.0 wt.% of the therapeutic formulation; tripeleannamine hydrochloride is present in about 0.5 wt.% to about 2.0 wt.% of the therapeutic formulation; hydrocortisone is present in about 0.25 wt.% to about 1.0 wt.% of the therapeutic formulation; corticosteroid is present in about 0.25 to about 5.0 wt.% of the therapeutic formulation; camphor is present in about 3 wt.% to about 10.8 wt.% of the therapeutic formulation with phenol; camphor is present in about 3 wt.% to about 10.8 wt.% of the therapeutic formulation with metacresol in about 1 wt.% to about 3.6 wt.% of the therapeutic formulation, as camphorated metacresol; or hydrocortisone acetate is present in about 0.25 wt.% to about 1.0 wt.% of the therapeutic formulation.

24. The adhesive patch of claim 22 wherein the hydrocortisone, the hydrocortisone acetate, or the combination thereof is present in about 0.25 wt.% to about 1.0 wt.% of the therapeutic formulation.

25. The adhesive patch of claim 22 wherein and the lidocaine, lidocaine hydrochloride, or the combination thereof is present in about 0.5 wt.% to about 4.0 wt.% of the therapeutic formulation.

26. The adhesive patch of claim 1 wherein the medicament is a corticosteroid.

27. The adhesive patch of claim 26 wherein the corticosteroid is at least one of cortisol (hydrocortisone); tetrahydrocortisol; prednisone (cortisone); prednisolone (cortisol); 6 α -methylprednisolone; fludrocortisone (9 α -fluorocortisol); 11-desoxycortisol; cortisone (11-

dehydrocortisol); corticosterone; triamcinolone (9α -fluoro- 16α -hydroxyprednisolone); paramethasone (6α -fluoro- 16α -methylprednisolone); betamethasone (9α -fluoro- 16β -methylprednisolone); dexamethasone (9α -fluoro- 16α -methylprednisolone); desoxycorticosterone acetate (doca acetate, percorten acetate); desoxycorticosterone pivalate (percorten pivalate); fludrocortisone acetate (florine acetate); cortisol (hydrocortisone) (cortef, hydrocortone); cortisol acetate (cortef acetate, hydrocortone acetate); cortisol cypionate (cortef); cortisol sodium phosphate (hydrocortone phosphate); cortisol sodium succinate (solu-cortef); beclomethasone dipropionate (vanceril); betamethasone (celestone); betamethasone sodium phosphate and acetate (celestone soluspan); betamethasone dipropionate (diprosone); betamethasone valerate (valisone); betamethasone benzoate (benisone, flurodate); cortisone acetate (cortone acetate); dexamethasone (decadron, gammacorten); dexamethasone sodium phosphate (decadron phosphate, hexadrol phosphate); dexamethasone acetate (decadron-L.A.); fuprednisolone (alphadrol); meprednisone (betapar); methylprednisolone (medrol); methylprednisolone acetate (depo-medrol, medrol acetate); methylprednisolone sodium succinate (solu-medrol); paramethasone acetate (haldrone); prednisolone (delta-cortef); prednisolone acetate (meticortelone acetate); prednisolone sodium phosphate (hydeltrasol); prednisolone sodium succinate (meticortelone soluble); prednisolone tebutate (hydelta-T.B.A.); prednisone (deltasone, paracort); triamcinolone (aristocort, kenacort); triamcinolone acetonide (aristoderm, kenalog); triamcinolone diacetate (aristocort diacetate, kienacort diacetate); triamcinolone hexacetonide (aristospan); desonide (tridesilon); desoximetasone (topicort); flumethasone pivalate (locorten); fluocinolone acetonide (fluonid, synalar); fluocinonide (lidex, topsyn); fluorometholone (oxylone); flurandrenolide (cordran); halcinonide (halog); medrysone (HMS liquifilm, medrocort); aclometasone dipropionate (alclovate); betamethasone-17-benzoate (benisone, flurobate); betamethasone dipropionate (diprosone); betamethasone-17-valerate (valisone); clobetasol propionate (temovate); desonide (desowen, tridesilon); dexamethasone (aeroseb-D); desoximetasone (topicort); diflorasone diacetate (florone); flumethasone pivalate (locorten); fluocinolone acetonide (synalar, synalar-HP, neosynalar, fluonid); fluocinolone acetonide acetate (lidex; lidex-E; topsyn); fluorometholone (oxylone); flurandrenolide (cordran); halcinonide (halog); hydrocortisone (cort-dome, lubricort); hydrocortisone acetate (cortef, carmol HC, neo-cortef); hydrocortisone-17-valerate (westcort); prednisolone (meti-derm); triamcinolone acetonide (kenalog, orabase, kenalog-S, mycolog, aristocort, aristocort-A, aristoderm, neo-aristoderm, neo-aristocort); temovate; diprolen; psorcon; temovate; diprolene; cyclocort;

diprosone; florone; halog; lidex; maxiflor; topicort; aristocort A; diprosone; florone; maxiflor; valisone; cordran; kenalog; synalar; topicort LP; westcort; cordran; diprosone; kenalog; locold; synalar; valisone; westcort; aclovate; desowen; locorten; synalar; tridesilone; valisone; hydrocortisone; dexamethasone; flumethalone; prednisolone; methylprednisolone; augmented betamethasone dipropionate (diprolene); diflorasone diacetate (psorcon); clobetasol propionate (temovate); halobetasol propionate (ultravate); amcinonide (cyclocort); betamethasone dipropionate (diprolene, diprosone); diflorasone diacetate (florone); halcinonide (halog); fluocinonide (lidex); diflorasone diacetate (maxiflor); betamethasone dipropionate (maxivate); diflorasone diacetate (psorcom); desoximetasone (topicort); (aristocort A); amcinonide (cyclocort); betamethasone dipropionate (diprosone); mometasone furoate (elocon); diflorasone diacetate (florone); halcinonide (halog); fluocinonide (lidex-E); diflorasone diacetate (maxiflor); betamethasone dipropionate (maxivate, psorion); betamethasone valerate (valisone); flurandrenolide (cordran); fluticasone propionate (cutivate); mometasone furoate (elocon); triamcinolone acetonide (kenalog); fluocinolone acetonide (synalar); hydrocortisone valerate (westcort); flurandrenolide (cordran); fluticasone propionate (cutivate); betamethasone dipropionate (diprosone); triamcinolone acetonide (kenalog); hydrocortisone butyrate (locoid); fluocinolone acetonide (synalar); betamethasone valerate (valisone); hydrocortisone valerate (westcort); alclometasone dipropionate (aclovate); triamcinolone acetonide (aristocort); desonide (desowen); flumethasone pivalate (locorten); fluocinolone acetonide (synalar); desonide (tridesilon); betamethasone valerate (valisone); hydrocortisone (eldecort, dexamethasone, flumethalone, hydrocortisone, methylprednisolone, or prednisolone); betamethasone; and dexamethasone.

28. The adhesive patch of claim 26 wherein the corticosteroid is present up to about 5 wt.% of the therapeutic formulation.

29. The adhesive patch of claim 1 wherein the solvent comprises a polyhydric alcohol, water, or a combination thereof.

30. The adhesive patch of claim 29 wherein the polyhydric alcohol is propylene glycol, ethylene glycol, triethylene glycol, or a combination thereof.

31. The adhesive patch of claim 30 wherein the propylene glycol is present in about 3.0 wt.% to about 11.0 wt.% of the therapeutic formulation.

32. The adhesive patch of claim 29 wherein the water is present in about 2.0 wt.% to about 20.0 wt.% of the therapeutic formulation.

33. The adhesive patch of claim 30 wherein the triethylene glycol is present in about 2.0 wt.% to about 20.0 wt.% of the therapeutic formulation.

34. The adhesive patch of claim 1 wherein the solvent is present in about 3.0 wt% to about 25.0 wt.% of the therapeutic formulation.

35. The adhesive patch of claim 1 wherein the solvent comprises water; triethylene glycol; glycerin; propylene glycol; triacetin; 1,3-propane diol; 2-methyl-1,3-propane diol; glycerol ricinoleate; PEG-6 caprylic / capric glycerides; caprylic / capric triglycerides; propyleneglycol dicaprylate / dicaprate; glycerol monostearate; glycerol monocaprylate; glycerol monolaurate; neopentyl alcohol; 1-hexadecanol; hydroxypropyl beta-cyclodextrin; vitamin E; vitamin E acetate; deoxycholic acid; taurodeoxycholic acid; 3-[(3-cholamidopropyl) dimethylammonio]-1-propane-sulfonate; BigCHAP; cholic acid; cholesterol NF; propylene carbonate; lecithin; a pharmaceutically acceptable salt thereof; or a combination thereof.

36. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises a filler.

37. The adhesive patch of claim 36 wherein the filler is malto dextrin.

38. The adhesive patch of claim 37 wherein the malto dextrin is present in about 1.0 wt.% to about 10.0 wt.% of the therapeutic formulation.

39. The adhesive patch of claim 1 wherein the pressure sensitive adhesive comprises one or more acrylic ester copolymers.

40.

The adhesive patch of claim 39 wherein each of the one or more acrylic ester copolymers is present up to about 20.0 wt.% of the therapeutic formulation.

41.

The adhesive patch of claim 39 wherein all of the one or more acrylic ester copolymers, combined, are present in about 5.0 wt.% to about 30.0 wt.% of the therapeutic formulation.

42.

The adhesive patch of claim 1 wherein the pressure sensitive adhesive is located on the entire surface of the front side of the backing.

43.

The adhesive patch of claim 1 wherein the pressure sensitive adhesive is at least partially embedded in the front side of the backing.

44.

The patch of claim 1 wherein the pressure sensitive adhesive is completely embedded in the backing.

45.

The adhesive patch of claim 1 wherein the pressure sensitive adhesive further comprises glycerin.

46.

The adhesive patch of claim 45 wherein the glycerin is present in about 25.0 wt.% to about 70.0 wt.% of the therapeutic formulation.

47.

The adhesive patch of claim 45 wherein the glycerin is present in about 40.0 wt.% to about 55.0 wt.% of the therapeutic formulation.

48.

The adhesive patch of claim 1 wherein the pressure sensitive adhesive further comprises an emulsifier.

49.

The adhesive patch of claim 48 wherein the emulsifier is pectin.

50.

The adhesive patch of claim 49 wherein the pectin is present in about 2.0 wt.% to about 10.0 wt.% of the therapeutic formulation.

51. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises a compound that provides structure and strength to the pressure sensitive adhesive or to the therapeutic formulation.

52. The adhesive patch of claim 51 wherein the compound that provides structure and strength to the pressure sensitive adhesive or to the therapeutic formulation is karaya, a polyacrylamide, xanthum gum, guar gum, a natural polymer, a synthetic polymer, a hydrophilic polymer, a hydrocolloidal polymer, starch, a starch derivative, vinyl acetate copolymer, polyvinyl pyrrolidone, polyethylene oxide, algin, derivatives of algin, a polyacrylate, polymaleic acid, polymaleic anhydride, a polyurethane, a polyurea, gum acacia, locust bean gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyvinyl alcohol, poly AMPS, or a mixture thereof.

53. The adhesive patch of claim 51 wherein the compound that provides structure and strength to the pressure sensitive adhesive or provides structure and strength to the therapeutic formulation is polyacrylamide.

54. The adhesive patch of claim 53 wherein the polyacrylamide is present in about 8.0 wt.% to about 30.0 wt.% of the therapeutic formulation.

55. The adhesive patch of claim 51 wherein the compound that provides structure and strength to the pressure sensitive adhesive or provides structure and strength to the therapeutic formulation is karaya.

56. The adhesive patch of claim 55 wherein the karaya is present in about 8.0 wt.% to about 40.0 wt.% of the therapeutic formulation.

57. The adhesive patch of claim 51 wherein the compound that provides structure and strength to the pressure sensitive adhesive or provides structure and strength to the therapeutic formulation is a combination of polyacrylamide and karaya.

58. The adhesive patch of claim 1 wherein the therapeutic formulation further

comprises one or more skin conditioners.

59. The adhesive patch of claim 58 wherein the skin conditioner is calamine, aloe, lanolin, glycerin, Vitamin E, Vitamin E acetate, farnesol, glycyrrhetic acid, or a combination thereof.

60. The adhesive patch of claim 59 wherein the aloe is present up to about 2.0 wt.% of the therapeutic formulation.

61. The adhesive patch of claim 59 wherein the Vitamin E acetate is present up to about 2.0 wt.% of the therapeutic formulation.

62. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises one or more antimicrobial agents.

63. The adhesive patch of claim 62 wherein the antimicrobial agent is a β -lactam compound, an aminoglycoside, or an antifungal agent.

64. The adhesive patch of claim 62 wherein the antimicrobial agent is erythromycin, tetracycline, clindamycin, cephalosporin, or a combination thereof.

65. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises one or more antiseptic agents.

66. The adhesive patch of claim 65 wherein the antiseptic agent is triclosan, phenoxy isopropanol, chlorhexidine gluconate, povidone iodine, or a combination thereof.

67. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises one or more preservatives.

68. The adhesive patch of claim 67 wherein the preservative is quat-15, methyl paraben, ascorbic acid, or a combination thereof.

69. The adhesive patch of claim 67 wherein the preservative is present up to about 1.5 wt.% of the therapeutic formulation.

70. The adhesive patch of claim 1 having a thickness of about 0.20 mm to about 0.75 mm.

71. The adhesive patch of claim 1 further comprising a release liner that is mounted on the front side of the backing.

72. The adhesive patch of claim 71 wherein more than one patch is mounted on the release liner.

73. The adhesive patch of claim 72 wherein about 2 to about 20 adhesive patches are mounted on the release liner.

74. The adhesive patch of claim 1 that is crescent, circular, or oval.

75. The adhesive patch of claim 74 wherein the circular adhesive patch has a diameter of about 0.1 inch to about 1.0 inch.

76. The adhesive patch of claim 1 wherein the therapeutic formulation further comprises a complexing agent that effectively solubilizes or stabilizes the medicament.

77. The adhesive patch of claim 76 wherein the complexing agent is a cyclodextrin, or a derivative of cyclodextrin.

78. The adhesive patch of claim 77 wherein the cyclodextrin or the derivative of cyclodextrin is alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, alpha-cyclodextrin sulfate, beta-cyclodextrin, sulfate, gamma-cyclodextrin sulfate, alpha-hydroxypropyl cyclodextrin, beta-hydroxypropyl cyclodextrin, gamma-hydroxypropyl cyclodextrin, alpha-cyclodextrin phosphate, beta-cyclodextrin phosphate, or gamma-cyclodextrin phosphate.

79. An adhesive patch comprising a flexible backing having a front side and a back side and a therapeutic formulation positioned on at least a portion of the front side of the backing, in at least a portion of the front side of the backing, or on and in at least a portion of the front side of the backing; wherein at least a portion of the backing is treated with a sizing agent such that the portion of the backing treated with the sizing agent has a surface energy of about 20 dynes/cm² to about 65 dynes/cm²; wherein the therapeutic formulation comprises:

- a corticosteroid;
- a cyclodextrin or a derivative of cyclodextrin that effectively solubilizes the corticosteroid; and
- a pressure sensitive adhesive.

80. An adhesive patch comprising a flexible backing having a front side and a back side and a therapeutic formulation positioned on and in at least a portion of the front side of the backing such that the therapeutic formulation is partially embedded in at least a portion of the front side of the backing; wherein at least a portion of the backing is treated with a sizing agent such that the portion of the backing treated with the sizing agent has a surface energy of about 20 dynes/cm² to about 65 dynes/cm²; wherein the therapeutic formulation comprises:

- salicylic acid or a pharmaceutically acceptable salt thereof present in about 0.5 wt.% to about 2.0 wt.% of the therapeutic formulation;
- a solvent that dissolves the salicylic acid; and
- a pressure sensitive adhesive.

81. An adhesive patch comprising a flexible backing having a front side and a back side and a therapeutic formulation positioned on at least a portion of the front side of the backing, in at least a portion of the front side of the backing, or on and in at least a portion of the front side of the backing; wherein at least a portion of the backing is treated with a sizing agent such that the portion of the backing that is treated with the sizing agent has a surface energy of about 20 dynes/cm² to about 65 dynes/cm²; wherein the therapeutic formulation comprises:

- a medicament selected from one or more topical psoriasis drugs, one or more topical dermatitis drugs, one or more topical eczema drugs, or a combination thereof; and
- a hot melt adhesive.

82. A method for treating or preventing at least one of psoriasis, dermatitis, and eczema in a mammal in need thereof comprising applying to the skin surface of the mammal having the psoriasis, dermatitis, or eczema or the skin surface of the mammal at risk thereof an adhesive patch of any one of claims 1, 79, 80, or 81 for a period of time effective to treat or prevent psoriasis, dermatitis, or eczema.

83. The method of claim 82 wherein the mammal is a human.

84. The method of claim 82 wherein the skin surface of the mammal having the psoriasis, dermatitis, or eczema or the skin surface of the mammal at risk thereof is the head, face, scalp, neck, shoulder, chest, back, arm, hand, leg, foot, navel, breast, underarm, groin, buttock, elbow, knee, eyelid, outer surface of the ear, gluteal fold, or any combination thereof.

85. The method of claim 82 wherein the period of time is about one hour to about 12 hours.

86. A method for exfoliating the skin surface of a mammal comprising applying to the skin surface of the mammal in need of such exfoliation an adhesive patch of any one of claims 1, 79, 80, or 81 and removing the adhesive patch, thereby effectively exfoliating the skin surface.

87. The method of claim 86 wherein the mammal is a human.

88. The method of claim 86 wherein the adhesive patch is applied to the skin surface of the mammal for about one second to about 12 hours.

89. The method of claim 86 wherein the skin surface in need of such exfoliation is the head, face, scalp, neck, shoulder, chest, back, arm, hand, leg, foot, navel, breast, underarm, groin, buttock, elbow, knee, eyelid, outer surface of the ear, gluteal fold, or any combination thereof.